UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

December 30, 1999

OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: Checklist for Reviewing EPA Quality Management Plans

FROM: Nancy W. Wentworth, Director
Quality Staff (2811R)

TO: EPA QA Managers

Attached is the Quality Management Plan (QMP) Checklist (Attachment 1) that the Quality Staff is using in its review of QMPs submitted for Agency approval by your organizations. I urge you to use this checklist to ensure that your organization's QMP is complete before it is submitted for approval and to attach the completed checklist to your submission.

This checklist was developed solely for the Quality Staff to use in reviewing Agency QMPs. However, you may use it to review QMPs submitted to your organization. If so, you will need to remove any requirements specific to EPA (see Attachment 2) and tailor the checklist to emphasize those elements important to your organization and the proposed work. Also, note that the checklist assumes a familiarity with EPA requirements.

This checklist was circulated for review in March 1999 and comments have been incorporated. Where applicable, comments were also incorporated into the document, *EPA Requirements for Quality Management Plans (QA/R-2)*. The checklist is consistent with both this document and Chapter 3 of EPA Manual 5360 (July 1998). The revised "Requirements" document will be finalized pending an announcement in the Federal Register by EPA's Office of Acquisition Management.

If you have any questions, please call me at (202) 564-6830. If you have specific questions about how your comments were addressed, contact Pat Lafornara at (732) 906-6988.

Attachments

ATTACHMENT 1
CHECKLIST FOR REVIEWING
EPA QUALITY MANAGEMENT PLANS

This checklist will be used to review the Quality Management Plans (QMPs) that are submitted to the Quality Staff of the Office of Environmental Information (OEI) for Agency review under EPA Order 5360.1 CHG 1. Items from this checklist are discussed in detail in EPA Manual 5360 Chapter 3 and in *EPA Requirements for Quality Management Plans (QA/R-2)*. Consult these resources for more information on the items below.

Note that all items below must be included in a QMP. If an item is not relevant, an explanation must be provided. Also note that process may either be described or referenced in the QMP; however, all references should be readily accessible within the organization and provided to the Quality Staff with the QMP.

	Page(s)	Comments
MANAGEMENT AND ORGANIZATION		
1. Signed and dated by senior manager?		
2. Signed and dated by senior line management?		
3. Signed and dated QA manager?		
4. Includes signature lines for Quality Staff approval?		
5. Includes signature lines for OEI approval?		
6. Includes statement of the organization's QA policy?		
6a. QA policy statement includes general objectives/goals?		
6b. QA policy statement includes allocation of intramural, extramural, and travel funds and personnel?		
7. Includes organizational chart?		

	Page(s)	Comments
7a. Organizational chart identifies all components of organization?		
7b. Organizational Chart identifies position of QA manager?		
7c. Organizational Chart identifies lines of reporting of the QA manager?		
7d. Organization Chart identifies any other QA staff?		
8. Includes discussion of authorities of the QA manager and staff?		
9. Documents the independence of QA manager?		
10. Describes procedures to ensure QA staff have access to appropriate levels of management?		
11. Discusses technical activities or programs that require quality management?		
12. Discusses where oversight of delegated or extramural programs is needed?		
13. Identifies where internal coordination of QA and QC activities among organizations is needed?		

	Page(s)	Comments
14. Discusses how management assures understanding and implementation in all programs?		
15. Describes process for resolving disputes?		
QUALITY SYSTEM COMPONENTS		
16. Includes description of quality system?		
17. Describes principal quality system components (e.g., quality system documentation, annual reviews and planning, project-specific quality documentation? (Note, identify components in Column 3.)		
18. Description of components includes how they are implemented?		
19. Description of components includes responsibilities of management and staff?		
20. Lists tools for implementing each component (e.g., QMPs, Quality Systems Audits, Training Plans, QA Project Plans? (Note: list tools in Column 3.)		
21. Identifies internal organizations that develop QMPs?		

	Page(s)	Comments
22. Identifies review and approval procedures for these internal QMPs?		
23. Includes assurance that QA responsibility is incorporated into performance standards (consistent with Agency personnel policy)?		
QUALIFICATIONS AND TRAINING		
24. States policy regarding QA training for management and staff?		
25. Describes process for identifying, ensuring, and documenting that personnel have necessary quality-related qualifications?		
26. Describes process for ensuring personnel maintain quality-related qualifications?		
27. Describes process for identifying the need for quality-related retraining based on changing requirements?		
28. Includes roles, responsibilities, and authorities in description of above processes?		
PROCUREMENT OF ITEMS AND SERVICES		

	Page(s)	Comments
29. Describes process for reviewing and approving all extramural agreements (grants, cooperative agreements and contracts)?		
29a. Review process ensures documents are complete and accurate?		
29b. Review process ensures agreement clearly describes the item or service needed?		
29c. Review process ensures agreement describes the associated technical and quality requirements?		
29d. Review process ensures agreement describes the quality system elements for which the supplier is responsible?		
29e. Review process ensures that the supplier's conformance to the customer's requirements will be verified?		
30. Describes process for reviewing and approving applicable responses to solicitations to ensure that they satisfy all technical and quality requirements?		
30a. Review process ensures the review of evidence of the supplier's capability to satisfy EPA quality requirements?		
30b. Review process ensures procured items and services are acceptable?		
31. Describes process for review and approval of suppliers' quality-related documentation (e.g., QA Project Plans and QMPs)?		
32. Includes discussion of any policy and criteria for delegations of review of QA Project Plans and QMPs?		

	Page(s)	Comments
33. Describes process to ensure EPA extramural agreement policies satisfied?		
34. Includes roles, responsibilities, and authorities in description of above processes?		

	Page(s)	Comments
DOCUMENTS AND RECORDS		
35. Describes process for identifying quality-related documents and records (including electronic) requiring control?		
36. Describes process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records?		
37. Describes process for ensuring that records and documents accurately reflect completed work?		
38. Describes process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?		
39. Describes process for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records?		
40. Above processes comply with EPA Order 2160 and EPA Directive 2100, Chapter 10?		
41. Includes roles, responsibilities, and authorities in description of above processes?		
COMPUTER HARDWARE AND SOFTWARE		

	Page(s)	Comments
42. Describes process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software?		
43. Is process consistent with EPA Directive 2182?		
44. Describes process for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?		
45. Describes process for evaluating purchased hardware and software?		
46. Describes process for ensuring that data and information produced from or collected by computers meet applicable requirements and standards?		
47. Includes roles, responsibilities, and authorities in description of above processes?		
48. Are the requirements of EPA Directive 2100 are addressed in the above processes?		

	Page(s)	Comments
PLANNING		
49. Includes a description of the systematic planning process for environmental data operations?		
49a. Does process include identification and involvement of all customers and suppliers?		
49b. Does process include description of the project goal, objectives, and questions and issues to be addressed?		
49c. Does process include identification of project schedule, resources, milestones, and any applicable requirements?		
49d. Does process include identification of the type and quantity of data needed and how the data will be used to support the project's objectives?		
49e. Does process include specification of performance criteria for measuring quality?		
49f. Does process include specification of needed QA and QC activities to assess the quality performance criteria?		
49g. Does process include description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection?		
49h. Does process include description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance criteria?		

	Page(s)	Comments
50. Describes process for developing, reviewing, approving, implementing, and revising QA Project Plans?		
51. Describes process for evaluating and qualifying data collected for other purposes or from other sources?		
52. Includes roles, responsibilities, and authorities in description of above processes?		
IMPLEMENTATION OF WORK PROCESSES		
53. Describes process for ensuring that work is performed according to planning and technical documents?		
54. Describes process for identifying operations needing procedures?		
55. Describes process for preparation, review, approval, revision, and withdrawal of these procedures?		
56. Describes policy for use of these procedures?		
57. Describes process for controlling and documenting the release, change, and use of planned procedures?		
57a. Process includes description of necessary approvals?		

	Page(s)	Comments
57b. Process includes removal of obsolete documentation from work areas?		
57c. Process includes verification that the changes are made as prescribed?		
58. Includes roles, responsibilities, and authorities in description of above process?		
ASSESSMENT AND RESPONSE		
59. Describes the process for assessing the adequacy of the quality system at least annually?		
60. Describes the process for planning, implementing and documenting assessments and reporting results to management?		
60a. Process includes selecting an assessment tool, the expected frequency, and the roles and responsibilities of assessors?		
60b. Process includes determining the level of competence, experience, and training needed for assessment personnel?		
60c. Process includes ensuring that personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?		
60d. Process includes ensuring that personnel conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom?		

	Page(s)	Comments
61. Describes process for management's review of, and response to, findings?		
62. Describes process for identifying how and when corrective actions are to be taken in response to the findings of the assessment?		
62a. Process includes ensuring corrective actions are made promptly?		
62b. Process includes confirming the implementation and effectiveness of any corrective action?		
62c. Process includes documenting actions?		
63. Describes process for addressing disputes encountered as a result of assessments?		
64. Includes roles, responsibilities, and authorities in description of above processes?		
QUALITY IMPROVEMENT		
65. Describes process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly and that actions are taken toward prevention, documented and actions tracked to closure?		

	Page(s)	Comments
66. Describes process for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?		
67. Includes roles, responsibilities, and authorities in description of above processes?		
OTHER REVIEW CRITERIA		
68. Are regulatory or other citations accurate?		
69. Are there any inconsistencies in the text?		
70. Is the writing clear?		
71. Are organizational units identified consistent with the most recent reorganization?		
72. Are past Quality Staff management assessment findings resolved? (Put date of Final Report in Column 3.)		
73. Are activities described in the QMP consistent with QA Annual Report and Work Plans?		
74. Are tasks proposed for other organizations not covered solely by this QMP documented elsewhere (e.g., in another organization's QMP)?		

ATTACHMENT 2
EPA-SPECIFIC QUALITY MANAGEMENT PLAN REQUIREMENTS

The following items from the *Checklist for Reviewing EPA Quality Management Plans* are only applicable for EPA QMPs required under EPA Order 5360.1 CHG 1 (July 1998):

4. Signature line for Quality Staff
5. Signature lines for OEI approval[1]
15. Dispute resolution process
23. Performance standards
30a. Review and approval of responses to solicitations to ensure they satisfy EPA quality requirements
31. Review and approval of quality-related documentation from suppliers
32. Policy and criteria for delegating approval of quality-related documentation
33. Process to ensure EPA contracting policies satisfied
40. Conformance to EPA Order 2160 and EPA Directive 2100, Chapter 10

[1]For non-EPA organizations, if EPA approval of a QMP is required, the approval page must include a section for the signature of the responsible EPA official.